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10 (54) Title of the Invention

Artificial Blood Vessel

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SPECIFICATION

1. TITLE OF THE INVENTION:

ARTIFICIAL BLOOD VESSEL

2. WHAT IS CLAIMED IS:

5 An artificial blood vessel comprising knitted and woven fabrics of fibers composed of monofilaments having a size without exceeding 1.0 denier

3. DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIELD OF THE INVENTION

10 The present invention relates to the improvement of an artificial blood vessel, particularly to the improvement of the artificial blood vessel comprising knitted and woven fabrics of fibers, more particularly to the improvement of an artificial blood vessel made of polyethylene terephthalate.

15 Viewed historically, the knitted and woven fabrics made of nylon and acryl-based derivatives were employed to produce an artificial blood vessel. At present, the mainstream artificial blood vessels include those made of polyethylene terephthalate and those made of polyethylene tetrafluoride. The present invention relates to the improvement of the artificial blood vessel comprising knitted and woven fabrics of fibers, particularly to the improvement of the artificial blood vessel comprising knitted and woven fabrics using polyester fibers, namely,

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polyethylene terephthalate spun fiber.

PRIOR ART

The current artificial blood vessel is required to meet wide-ranging requirements as exemplified by requirements
5 for freedom from toxicity, elimination of reaction to foreign substances, superb durability without being deteriorated, appropriate elastic extensibility, antithrombogenicity, superb organized healing, easy suture, capability for assuming varied forms, minimized blood
10 leakage and immunity to infection.

The polyester-based synthetic fiber is frequently used as an artificial blood vessel because of excellent chemical stability, durability and minimized reaction to tissue. In this case, tubular weaving or knitting is employed.

15 The biggest problem with the current artificial blood vessel is found in the chronological constriction or blocking of the blood vessel caused during usage subsequent to transplantation, and blood circulation failure due to kinking (breakdown by bending) or blood coagulation
20 resulting therefrom. After the artificial blood vessel has been transplanted, a thrombotic film is formed through the processes of adsorption of plasma protein and ensuing adsorption of blood cell components such as thrombocytes and erythrocytes, which are followed by the processes of segregation of fibrin and formation of a fibrin film. The
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segregated fibrin is replaced by a cell, and a pseudo-endothelium and fibrous epithelium are formed based thereon. These membranes are then formed into a biological substance. The formation of this biological substance is essential to
5 ensure the function of a vessel for stabilized blood circulation. This requires the artificial blood vessel to have an appropriate level of porosity (porous rate). When the artificial blood vessel having been developed so far is applied to the micro-artery and micro-vein having a
10 diameter without exceeding 4 mm, early obstructive thrombus is caused at a higher rate. Thus, various research and development efforts are being made for improvement. However, no satisfactory solution has been found out at present.

PROBLEMS TO BE SOLVED BY THE INVENTION

15 Relating to the improvement of the artificial blood vessel produced by knitting and weaving of fibers, particularly to the improvement of the artificial blood vessel produced by knitting and weaving the polyester-based polyethylene terephthalate synthetic fibers, the present invention intends to provide a flexible artificial blood vessel suited for the growth of endothelial cells. The present invention further intends to provide an artificial blood vessel characterized by protection against kinking, and an artificial blood vessel characterized by superb
20 capability of restoring the original diameter when released
25

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from a load.

In the conventional art, the tubular artificial blood vessel made of polyester-based knitted and woven fabrics is provided with a process of pleating in order to eliminate
5 the possibility of kinking. This pleated artificial blood vessel can be bent free from kinking. Further, this process of pleating (also called the crimping) allows the
artificial blood vessel to expand and contract along the length. After the artificial blood vessel has been
10 transplanted, endothelial cells grow inside the blood vessel, and the artificial blood vessel is formed into a biological substance. During this process, the artificial blood vessel may contract. If provided with pleating at this time, the artificial blood vessel is provided with
15 sufficient extensibility. This solves the problem without the tissue of anastomosed site being pulled. In the meantime, the artificial blood vessel made of fluorine resin based EPTFE (Expanded Polytetrafluoroethylene -- expanded fibrinated polytetrafluoroethylene) has its outer
20 surface reinforced with a synthetic resin tape or monofilament provided in the shape of a ring to avoid kinking. This method eliminates the possibility of kinking to a considerable extent. However, the artificial blood vessel will contract during the long-time use, and
25 unfavorable tension is applied to the sutured region

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because of lack of elasticity along the length of the artificial blood vessel. This may cause distortion of the anastomosed site which, in turn, may cause a thrombus to be formed at this portion, with the result that an
5 archesporial cell will be produced in the endothelium. This may cause the anastomosed region to be constricted, and an internal obstruction may be caused eventually. Particularly in the artificial blood vessel of a smaller diameter, this problem tends to arise more conspicuously. This shows how
10 the practical use of this method has been delayed.

MEANS FOR SOLVING THE PROBLEMS

The present inventor has made concentrated study efforts to develop an artificial blood vessel characterized by excellent extensibility along the length, a high degree
15 of resistance to kinking, and superb recoverability wherein the artificial blood vessel having been flattened by the applied load can be recovered to the original diameter when the load has been removed. In these study efforts, the artificial blood vessel made of a tube formed by knitting
20 and weaving of such a synthetic fiber as polyethylene terephthalate was provided with a process of pleating in a spiral form. This artificial blood vessel was reinforced in a spiral form by the synthetic resin, metallic monofilament or elastic monofilament along the valley portion of the
25 spiral pleat. It has been found out that this artificial

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blood vessel is provided with such excellent extensibility along the length that the possibility of causing kinking is successfully eliminated, and recoverability to the original diameter is ensured.

5 A fiber made of such a material as polyethylene terephthalate, collagen and tetrafluoro ethylene is employed as the synthetic fiber for knitting and weaving the artificial blood vessel used in the present invention. The fiber made of polyethylene terephthalate is most
10 preferably used. The present inventor has found out that, from the viewpoint of flexibility of the knitted and woven fabric, the fiber made of the material used for knitting and weaving of the artificial blood vessel can be more preferably utilized when the size of the monofilament is
15 greater. In the conventional art, the artificial blood vessel of synthetic fiber is obtained by knitting and weaving the fiber having a size of 1.0d (denier) or more, normally in the range from 2.0 through 5.0d. The present inventors produced an artificial blood vessel using the
20 ultra-thin polyester fibers having sizes of 1.0d or less, namely, 0.8, 0.6, 0.3 and 0.1d. These fibers were pleated in a spiral form to produce an artificial blood vessel on a tentative basis. It has been found out that, by adjusting the grain of fabric in knitting and weaving it is possible
25 to produce the artificial blood vessel characterized by

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superb flexibility and wide-ranging porosity (which represents the amount of per-minute water outflow in a pressurized operation of 120 mmHg/cm² in terms of the amount of water passing through the tube wall according to the
5 method of Wesolwski (Wesolwski, S.A. Fundamentals of Vascular grafting, McGraw-Hill Book Co., New York, 1963) wherein the unit is given in cc/min/cm²). This porosity can be adjusted within the range from 30 through 5,000
cc/min/cm². Normally, this porosity is essential to ensure
10 that endothelial cells grow on the inner wall of the artificial blood vessel. If the porosity is excessive, blood leakage will occur. To prevent this, pro-clotting operation is performed in advance, wherein the artificial blood vessel is processed by the blood of a patient to
15 cause blood coagulation among fibers, whereby the space is filled. When the artificial blood vessel is produced by knitting and weaving ultra-thin constituent monofilaments having a size of 1.0d or less as in the present invention, it is possible to produce the artificial blood vessel
20 characterized by the minimized blood leakage (minimized porosity) and superb flexibility, wherein smooth growth of the endothelial cells is ensured. To manufacture the artificial blood vessel by knitting and weaving the conventional monofilaments having a size of 1.0d or less,
25 close knitting and weaving are essential, if an attempt is

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made to reduce the porosity and to minimize the blood leakage. This will harden the artificial blood vessel and anastomosis will be difficult. When carrying out a surgical operation, smooth anastomosis cannot be performed, and problems are raised. There has been no flexible artificial blood vessel characterized by flexibility or capability of favorable growth of endothelial cells. There has been an intense demand for such a product. The present inventor used the polyester fiber made of ultra-thin filaments with a size of 1.0d or less to produce the artificial blood vessel characterized by excellent flexibility, minimized blood leakage and capability of ensuring favorable growth of endothelial cells. To be more specific, healing is encouraged by the artificial blood vessel of the present invention produced by knitting and weaving of polyester fibers with a size of 1.0d or less (hereinafter referred to as "monofilament"). Whereas the conventional product requires 4 months for the growth of the pseudo-endothelium in the case of a dog and one year in the case of humans, the artificial blood vessel of the present invention requires only two months for the growth of endothelium grow according to a test conducted on a dog. Further, the artificial blood vessel of the present invention is characterized by very soft texture and every easy transplantation to the blood vessel and anastomosis. This

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is very important. It is not too much to say that success or failure of a surgical operation in the transplanted blood vessel depends on the state of anastomosis. For anastomosis, good suturing property plays an extremely
5 important part.

Using the synthetic fiber composed of ultra-thin monofilaments having a size of 1.0d or less, especially the polyester terephthalate fiber, the present inventor produced a pleated artificial blood vessel. This has
10 provided an artificial blood vessel that has been long desired for--an artificial blood vessel characterized by minimized blood leakage and easy anastomosis. What is more noteworthy is that, by using the artificial blood vessel formed by knitting and weaving the polyester fiber composed
15 of ultra-thin monofilaments having a size of 1.0d or less, the thickness of the thrombus layer generated after transplantation of the blood vessel is reduced to the level much smaller than that of the conventional product,
although the reason is yet to be found out. Further, the
20 endothelium that grows to be formed into a biological substance is thinner without an archesporial cell having been identified. To be more specific, in the conventional artificial blood vessel made of Dacron (R), the thickness of the thrombus layer produced on the endothelium of the
25 artificial blood vessel subsequent to transplantation

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normally reaches the level of 1 mm. This thrombus layer is absorbed by the endothelial cell grown thereon, but the endothelium itself tends to grow into an archesporial cell. It has been observed that the archesporial cell of the 5 endothelium is more conspicuously as the original thrombus layer is thicker. By contrast, in the artificial blood vessel of the present invention composed of the ultra-thin polyester fiber, the thickness of the thrombus layer grown in the initial phase is 0.1 through 0.5 mm, although the 10 reason is not yet clear. Even if an endothelium grows thereon, the inner diameter of the actual artificial blood vessel is not constricted practically. The prevent inventor has found out this interesting phenomenon. The present 15 inventor produced the polyester-made artificial blood vessels of small diameter using this ultra-thin fiber, and transplanted the same to the intestinal artery and femoral artery. Obstruction occurred within three days in the conventional product. By contrast, the artificial blood vessel of the present invention was found to be completely 20 patent even after six months, and served the functions of an artificial blood vessel of small diameter.

The following describes the details of the validity of the artificial blood vessel which is provided with the processing of spiral reinforcement to avoid kinking. In 25 recent years, there has been an increase in the number of

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5 peripheral vessel disorders with the increase in the population of aged people resulting from lengthened life span. Peripheral blood vessels indicate the blood vessels above and below elbows, and those above and below knees,
10 especially those below the waist. In this case, the disorder is removed by replacing faulty blood vessel with an artificial blood vessel. This eliminates the need of amputating the hand or foot, and ensures the normal function to be restored. Thus, there has been an intense demand for an artificial blood vessel for peripheral vessel.
15 An artificial blood vessel for peripheral vessel is required to ensure (1) excellent patency of the blood vessel, and (2) and immunity of the blood vessel from being kinked or crushed when bent or pressed by bending of the hands and feet, or easy recoverability to the original state even after being crushed slightly.

In the conventional art, an attempt has been made to use fluorine resin to reinforce the blood vessel by filament-like synthetic resin. The artificial blood vessel of fluorine resin has no elasticity along the length of the blood vessel. Thus, the problem of shrinkage in the process 20 of healing has not been solved in the conventional art.

The present inventor applied the process of pleating the knitted and woven fabric of synthetic fiber in the form 25 of a spiral. This artificial blood vessel was reinforced by

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synthetic resin, metallic monofilament or elastic monofilament along the valley portion of the spiral pleat. In this case, a rigid member of synthetic resin or elastic monofilament is used for reinforcement as a bonding agent.

5 Vinyl polychloride, vinylidene polychloride, polyethylene, polypropylene, polyethylene terephthalate, or nylon is used as the material of the rigid monofilament. This is mainly intended by prevent the diameter from being flattened by weight. The monofilament of polyethylene, 10 polypropylene or vinyl polychloride adheres closely to the spiral valley by contraction caused by heating, and part of the surface of the monofilament is softened or is made into semi-molten state so that the monofilament penetrates the mesh of the polyester fiber, whereby the required power of 15 bonding is ensured. The above-mentioned monofilaments are preferably oriented to a greater extent by drawing so as to get a high-strength fiber of 3 g/d or more.

In the process of spiral reinforcement, the fabric can be wound on a metallic rod having a circular section in 20 advance and is heat-treated. The spring-like monofilament shaped in a spiral form can be used, for example. Alternatively, a linear fabric can be wound along the valley of the spiral pleat of the artificial blood vessel, and can be heat-treated. In the process of bonding for 25 reinforcement, the pleated artificial blood vessel to be

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reinforced is coated on a metallic rod, and is wound along the valley. Under this condition, heat treatment is provided so that part of the contracted surface of the monofilament as a reinforcing member is made into a semi-molten state, whereby bonding is performed.

The temperature for heat treatment is preferably above the softening point and below the melting point. The temperature can be above the melting point if for a short time. Even if the temperature of the atmosphere for treatment is raised above the melting point, the surface starts to melt first, without the entire polymer being molten together. This mechanism can be utilized. However, to ensure safety, treatment is preferably performed at a temperature closer to and below the melting point.

The preferred treatment temperature is about 90°C for polyethylene, and about 120°C for polypropylene.

In this case, reinforcement by synthetic resin monofilaments need not be provided over the entire region of the artificial blood vessel. For example, reinforcement can be provided 5 cm through 15 cm at the center of the artificial blood vessel. The operator is only required to perform transplantation and surgical operation in such a way that the spirally processed portion will be located at the elbow or knee as the bending member. This method is advantageous in that suturing is easy wherein anastomosis

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is performed actually because there is no spiral reinforcement. Thus, this method is very useful and is important from the viewpoint of performing surgical operations. Such a partially reinforced artificial blood vessel is not present as yet.

The present invention also provides a partially spiral-reinforced blood vessel from such a practical viewpoint.

The present invention has found out that very interesting results can be provided when an elastic monofilament is used to reinforce the pleated artificial blood vessel.

A naturally occurring rubber can be used as the elastic monofilament. However, a polyurethane elastic fiber is preferably used for excellent stability and biocompatibility. Polyether based polyurethane or polyurethane urea is excellent for in-vivo stability as the polyurethane. Polyester based polyurethane can also be utilized.

The elastic fiber known under the name of spandex fiber is preferably utilized. For example, the Lycra (R) fiber and Oesten (R) fiber can be used.

The polyether portion thereof is made of polytetramethylene glycol. The fabric wherein the molecular weight of this component is 1000 through 2000 is preferably employed. 4,4'-diphenylmethane diisocyanate or toluidine

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diisocyanate is used as the diisocyanate used for preparation.

The former substance is preferably used for medical services. Diamine and diol such as ethylene diamine and 5 butane diol are used as chain elongation agent for synthesis of polyurethane.

The commonly known polyurethane is widely used in addition to the above-mentioned examples as the polyurethane used in the present invention.

10 The polyurethane filament is wound along the pleated valley, and the end of this filament is bonded to perform processing for reinforcement. To ensure that the wound elastic monofilament is closed bonded onto the tissue of the artificial blood vessel, the solvent of tetrahydrofuran, 15 dioxane, dimethylformamide, dimethyl acetoamide and the like as the solvent of polyurethane, or the solution obtained by dissolving polyurethane into these solvent is brought in contact with the wound portion by spraying, immersion or brushing, whereby the power of adhesion can be improved. A load is applied to the artificial blood vessel 20 wherein such an elastic filament is wound along the pleated valley thereof, until the artificial blood vessel is crushed. After that, this load is removed. Then the portion of the elastic monofilament crushed by the elastic 25 action recovers to the original circular diameter. For the

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5 peripheral vessel used through the bending portion of the elbow or knee, this arrangement can be applied effectively to the hysteresis due to the expansion and contraction of the knee and elbow to which the artificial blood vessel is constant exposed. Thus, this arrangement provides a means for solving the hitherto unsolved problem with recovery of the peripheral vessel to the original diameter.

EFFECTS OF THE INVENTION

10 As described above, the valley of the pleat of the spirally pleated artificial blood vessel is reinforced by the spiral of the filament made of synthetic resin or elastic body, whereby the possibility of kinking is completely eliminated. Further, the effect of pleating permits extension and contraction of the artificial blood
15 vessel along the length. The artificial blood vessel of the present invention serves a useful function as a material for peripheral vessel transplantation. Further, since the synthetic fiber composed of ultra-thin monofilaments having a size of 1.0d or less is used, the artificial blood vessel
20 is soft, and exhibits excellent anastomotic properties and a high rate of patency.

EXAMPLE 1

25 The tubes of various diameters shown in the following Table were produced by plain weaving and knitting, using the synthetic fiber composed of polyester fibers (Tetron

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(R) fibers) having sizes of 0.6d, 0.3d, and 0.1d. These tubes were pleated (spiraled) according to the conventional method.

These tubes were provided with spiral reinforcement
5 (see the Example) using a polypropylene monofilament, and
were transplanted to the iliac artery of an adult dog of
mixed breed by end-to-end connection method. The thickness
of a thrombus membrane three days later, and patency one
week later and patency four weeks later were checked,
10 without any anticoagulant such as heparin being
administered. The following Table shows the results of this
test.

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As will be apparent from this Example, in the thin polyester fiber with a size of 1.0d or less, the thrombus layer generated in the earlier phase is very thin. This has
5 a serious impact on the patency. The advantage of using the ultra-thin fiber is clearly demonstrated.

EXAMPLE 2

The atelocollagen fiber having a size of 0.6 denier was plain woven and to get a 3-mm tube. This tube was pleated,
10 and the valley of the pleat was provided with spiral reinforcement using a polypropylene monofilament. This tube was transplanted to the femoral artery of an adult dog of mixed breed by end-to-end connection method. The thickness of a thrombus layer one week later was 0.3 mm.

15 The same test was conducted on another adult dog to check the long-term patency. The transplanted blood vessel was patent three weeks later.

EXAMPLE 3

Using polyester fibers (Tetron ®) with a size of 0.3d,
20 tubular woven fabrics having an inner diameters of 3 mm, 4 mm, 8 mm and 10 mm were woven by plain weaving and were provided with spiral pleating. The pleated blood vessels were passed through the stainless steel rods having outer diameters of 2.9 mm, 3.8 mm, 7.8 mm and 9.8 mm, and the spiral polypropylene monofilaments prepared in advance were
25

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arranged along the valley of the pleat. These blood vessels were heat-treated at 155°C, whereby the spirals of the polypropylene monofilaments were contracted to come into close contact along the valley of the artificial blood vessel. The artificial blood vessels reinforced with polypropylene spirals were cut to a length of 15 cm. Both ends were crossed to examine the curvature of the center wherein kinking occurred. The following Table shows the results of this test:

10

| Inner diameter of artificial blood vessel | Spiral reinforcement | | Curvature wherein kinking occurs mm |
|---|----------------------|--------------|-------------------------------------|
| | Provided | Not provided | |
| 3 mm | Provided | | 2.0 |
| 3 mm | | Not provided | 4.5 |
| 4 mm | Provided | | 2.5 |
| 4 mm | | Not provided | 5.0 |
| 6 mm | Provided | | 6.0 |
| 6 mm | | Not provided | 12.0 |
| 10 mm | Provided | | 8.0 |
| 10 mm | | Not provided | 16.0 |

15

20

The Table clearly demonstrates that the artificial blood vessels provided with spiral reinforcement ensure greater resistance against kinking.

EXAMPLE 4

Artificial blood vessels of polyester fiber having inner diameters of 3 mm and 6 mm were provided with spiral pleating, and the polyurethane monofilaments (spandex fibers) were wound along the valleys of pleats. When these

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monofilaments were wound, a slight tension was applied to polyurethane to the extent wherein the diameter of the artificial blood vessel would not be bent. The end portions were bonded by polyurethane dope. The adhesive property 5 between the polyurethane filament and artificial blood vessel can be improved by applying with a brush or spraying the solution obtained by dissolving the polyurethane of the same or different type in tetrahydrofuran, dioxane, dimethyl acetamide, dimethylformamide or the solvent thereof, onto the top of the polyurethane filaments having 10 been wound.

The polyurethane having been used includes polytetramethylene glycol as a polyether component, and 4,4'-diphenylmethanediisocyanate, hexamethylene 15 diisocyanate as isocyanate components. As a chain elongatyon agent, ethylene diamine, propylene diamine, butanediol wave used.

The fiber having the aforementioned elastic polyurethane fiber arranged in the valley portion of the 20 pleat was pressed at a pressure of 100 g/cm² for 20 minutes and one hour. After that, pressure was removed to examine the degree of recovery to the original diameter. A complete recovery was observed in all the products reinforced by elastic polyurethane fiber. By contract, the diameters of 25 other products remained flattened as before.

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The following Table summarizes the results of this test:

| | Inner diameter of artificial blood vessel | Elastic polyurethane fiber *1 | Pressure time and recovery rate | | |
|----|---|-------------------------------|---------------------------------|------------|------------|
| | | | Immediately after | 20 minutes | 60 minutes |
| 5 | 3 mm | Oesten *2 | 75 | 80 | 100 |
| | 6 mm | Oesten *2 | 70 | 75 | 95 |
| | 3 mm | - | 20 | 25 | 100 |
| | 3 mm | Beresen *3 | 70 | 85 | 95 |
| | 6 mm | Beresen *3 | 60 | 75 | 80 |
| | 6 mm | - | 15 | 20 | 27 |
| 10 | 3 mm | Adiprene *4 | 75 | 85 | 98 |
| | 6 mm | Adiprene *4 | 60 | 75 | 90 |
| | 3 mm | Lycra *5 | 85 | 90 | 100 |
| | 6 mm | Lycra *5 | 70 | 85 | 95 |
| | | | | | |
| | | | | | |

* Recovery to the original diameter (%) after removal of electric charge

*1 Test piece having a diameter of 0.8 mm

20 *2 (Chain elongation agent, butanediol by Goodrich)

*3 (by Adjohn)

*4 *5 (Chain elongation agent, ethylene diamine by Du Pont)

EXAMPLE 5

25 Using the polyester fiber having a monofilament size of 0.2d, Teton artificial blood vessels with diameters of 3 mm, 4 mm, and 6 mm were woven by plain weaving. These artificial blood vessels were provided with spiral pleating in the conventional method. The pleated artificial blood

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vessel had a length of 40 cm. Spandex fiber Lycra (outer diameter: 0.7 mm) was wound in the valley of the pleat 15 cm at the center of this fiber. Then 20 percent solution obtained by dissolving the polyurethane made of the same components in dimethyl acetoamide was applied with a brush onto the top of the portion wound with this spandex fiber. This was dried and was sufficiently extracted by hot water to remove the solvent. Thus, in the product obtained, the portion of about 15 cm was reinforced by the elastic polyurethane fiber, and the reinforced portion was coated with a thin layer of polyurethane. The Lycra filament was bonded integrally with the coated polyurethane film. A load of 200 g/cm² was applied to the polyurethane processed portion of the artificial blood vessel treated in this manner. This load was removed ten minutes after this pressure was applied, and the recovery of this portion to the original state was examined. Immediately after the load was removed, the original state was recovered from the flattened state. In five minutes, the original circular form was restored perfectly.

The polyurethane-treated portion of the aforementioned artificial blood vessel is arranged at such a bending portion as the elbow and knee, and is transplanted to the peripheral vessel. This arrangement ensures recovery from kinking caused by expansion and contraction of the knee and

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elbow.

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